NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ORTHO-MCNEIL PHARMACEUTICAL, INC.,	x	
Plaintiff,	x	
	x	Civil Action Nos. 04-1689, 06-757 and 06-5166 Consolidated Cases
v.	x	
	x	**OPINION**
MYLAN LABORATORIES INC., et al.,	x	
Defendants.	x	

CHESLER, District Judge

This matter comes before the Court on the motion by Plaintiff Ortho-McNeil Pharmaceutical, Inc. ("Ortho") for partial summary judgment, pursuant to FED. R. CIV. P. 56, on the defense of Defendants Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (collectively "Mylan") asserting that the patent in suit is invalid for obviousness. For the reasons stated below, Ortho's motion for partial summary judgment is **GRANTED**.

BACKGROUND

This is a patent infringement case brought under the Hatch-Waxman Act. Ortho claims that, on April 23, 1985, the United States Patent and Trademark Office ("PTO") issued United States patent number 4,513,006 (the "'006 patent") to McNeilab, Inc. as assignee of inventors Bruce E. Maryanoff and Joseph F. Gardocki. (Compl. ¶ 10.) McNeilab is Ortho's corporate predecessor. (Id.) The claims of the '006 patent cover the drug topiramate, pharmaceutical

compositions containing topiramate, and a method of using topiramate to treat convulsions. (Id. ¶ 11.) Ortho holds an approved New Drug Application ("NDA"), under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 335(a), for topiramate tablets and topiramate capsules, which are marketed in the United States as the anticonvulsant TOPAMAX®. (Id.)

In 2001, Mylan filed an Abbreviated New Drug Application ("ANDA"), pursuant to Section 505(j) of the FFDCA, to market topiramate 25, 50[1], 100, and 200 mg tablets before the expiration of the '006 patent. (Id. at ¶ 14.) In its ANDA, Mylan claimed that the '006 patent is invalid and, therefore, that none of its claims would be violated by Mylan's manufacture, use, and sale of topiramate. (Id. at ¶ 15.) On March 2, 2004, Mylan served Ortho with notice of its position and intent to seek approval to market topiramate before the expiration of the '006 patent, triggering the running of the 30-month period staying FDA action. (Id. at ¶ 16.) Anticipating the expiration of the 30-month stay in September, 2006, on July 14, 2006, Ortho moved for a preliminary injunction, which this Court granted on October 23, 2006, preliminarily enjoining Mylan from marketing or selling topiramate.

All of the disputes in this case over Mylan's patent invalidity defenses have been resolved but one: Mylan's defense of patent invalidity due to obviousness. At the preliminary injunction

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[1] The Complaint filed in Civil Action No. 04-1689 alleged infringement of the '006 patent based on Mylan's filing an ANDA with respect to topiramate 25, 100, and 200 mg tablets. Mylan subsequently amended its ANDA to include 50 mg tablets and Ortho filed another lawsuit to address that dosage, under Civil Action No. 06-757. On May 17, 2006, Magistrate Judge Bongiovanni entered an Order consolidating these matters. [Civil Action No. 04-1689, Docket Entry No. 129.] On December 21, 2006, Civil Action No. 06-5166, in which Ortho alleged infringement of the '006 patent based on Mylan's filing an ANDA with respect to topiramate 15 and 25 mg capsules, was also consolidated into this case.

hearing held on October 12, 2006, the Court instructed the parties that it would entertain a motion for partial summary judgment on this issue. Ortho then made the instant motion for partial summary judgment.

LEGAL STANDARD

I. Summary Judgment

Summary judgment is appropriate under FED. R. CIV. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255).[2]

"When the moving party has the burden of proof at trial, that party must show affirmatively the absence of a genuine issue of material fact: it must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." In re Bressman, 327 F.3d 229, 238 (3d Cir. 2003) (quoting United States v. Four Parcels of Real Property, 941 F.2d 1428, 1438 (11th Cir. 1991)). "[W]ith

[2] In patent cases, a district court applies its circuit's law of summary judgment. See CollegeNet Inc. v. ApplyYourself Inc., 418 F.3d 1225, 1230 (Fed. Cir. 2005).

respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by 'showing' – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party's case." Celotex, 477 U.S. at 325.

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. Jersey Cent. Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. Anderson, 477 U.S. at 248; Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). "[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990); see also FED. R. CIV. P. 56(e) (requiring nonmoving party to "set forth specific facts showing that there is a genuine issue for trial"). "A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial." Gleason v. Norwest Mortg., Inc., 243 F.3d 130, 138 (3d Cir. 2001).

If the nonmoving party has failed "to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial, . . . there can be 'no genuine issue of material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Katz v. Aetna Cas. & Sur. Co., 972 F.2d 53, 55 (3d Cir. 1992) (quoting Celotex, 477 U.S. at 322-23).

II. Patent validity

"A patent shall be presumed valid." 35 U.S.C. § 282. "[A]n accused infringer who raises patent invalidity as a defense bears the burden of showing invalidity by facts supported by clear and convincing evidence." Robotic Vision Sys. v. View Eng'g, Inc., 189 F.3d 1370, 1377 (Fed. Cir. 1999).

III. Non-obviousness

To patent an invention, the subject matter must be non-obvious:

> A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. § 103(a).

"It is well-settled that obviousness is a legal question based on underlying factual determinations." Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1323 (Fed. Cir. 2004) (quotation omitted).

> [F]actual determinations relevant to the obviousness inquiry include: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations, if any, such as commercial success, unexpected results, copying, long-felt but unresolved need, and the failure of others to develop the invention.

Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371, 1378 (Fed. Cir. 2005).

The Federal Circuit emphasizes the importance of eliminating the influence of hindsight in the obviousness inquiry through application of the "motivation-suggestion-teaching" test. In re Kahn, 441 F.3d 977, 986 (Fed. Cir. 2006).

> [T]he best defense against the subtle but powerful attraction of a hindsight-based

> obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. . . Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of hindsight.

In re Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999) (citations omitted). Moreover, "an obviousness determination requires not only the existence of a motivation to combine elements from different prior art references, but also that a skilled artisan would have perceived a reasonable expectation of success in making the invention via that combination." Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1165 (Fed. Cir. 2006).

DISCUSSION

I. Plaintiff's Motion for Summary Judgment on the Obviousness Invalidity Defense.

Ortho moves for partial summary judgment by arguing, on several grounds, that Mylan's case for obviousness suffers from fatal defects, any one of which renders Defendant unable to prevail as a matter of law. Mylan attempts to refute these points, but does not succeed.

A. An obviousness argument cannot be based on the path taken by the inventor

Ortho contends that Mylan's theories rely on following the path taken by the inventor, which cannot be used to show obviousness. Mylan responds that this is "not so" and that their expert, Dr. Anderson, "analyzed the compound claims independently of any motivation that Maryanoff might have had as a matter of historical fact." (Defs.' Opp. Br. 12.) Dr. Anderson's own words do not support Mylan's assertion.

Dr. Anderson's expert report of April 27, 2005 traces a path to the invention. The path begins at this point:

> Materials produced during discovery indicate that in early 1978 Dr. Maryanoff became interested in the possibility of preparing inhibitors of the enzyme [FBPase]. He thought such inhibitors might be useful in controlling the level of blood sugar (glucose) in diabetic patients, since FBPase is a key enzyme in the metabolic pathway used by our bodies to produce glucose from nonsugar precursors.

(Anderson Decl. Ex. A. ¶ 11.) From this point, Dr. Anderson followed the path of ideas that Dr. Maryanoff described in his New Product Conception Record of April 1978, leading to the synthesis of topiramate. (Id. at ¶¶ 12-22.) In Dr. Anderson's declaration, he states:

> It is my understanding that the requisite motivation to modify a prior art reference can be found in the nature of the problem to be solved. In my Expert Report, I detailed the work performed by Maryanoff, one of the named inventors of the '06 patent, *in order to show the nature of the problem faced by Maryanoff* and as evidence of how one of ordinary skill in the art would solve that problem. It is important to remember that *the problem faced by Maryanoff* . . .

(Anderson Decl. ¶ 4 (italics added)). As his final statement, Dr. Anderson concludes: "Given the nature of the problem to be solved by Dr. Maryanoff, a person of ordinary skill in the art would have been motivated to synthesize topiramate and would have had a reasonable expectation that such a synthesis would be successful." (Id. at ¶ 13.)

As is clear from these passages, Mylan's assertion that Dr. Anderson analyzed the compound claims independently of Maryanoff's motivation is untrue. To the contrary, Dr. Anderson's analysis tracks Maryanoff's thinking closely, expressly referring to the ideas Dr. Maryanoff wrote down in the New Product Conception Record.

The Federal Circuit has made clear that the inventor's chosen path is irrelevant: "[T]he path that leads an inventor to the invention is expressly made irrelevant to patentability by statute. . . [T]his inquiry, as a matter of law, is independent of the motivations that led the inventors to the claimed invention." Life Techs., Inc. v. Clontech Lab., Inc., 224 F.3d 1320,

1325 (Fed. Cir. 2000). Rather, § 103(a) requires that the obviousness inquiry must be performed from the perspective of one of ordinary skill in the art.

Because the obviousness inquiry must be independent of the motivations of the inventor, and because Dr. Anderson used Dr. Maryanoff's motivations to structure his theories, his theories are legally insufficient. Mylan has not presented even a theory of obviousness – no less a theory supported by evidence – that is fully independent of Dr. Maryanoff's motivations.

The Federal Circuit has repeatedly warned against hindsight-based obviousness analysis. See, e.g., Alza Corp. v. Mylan Labs., Inc., 464 F.3d 1286, 1290 (Fed. Cir. 2006) (discussing "our anti-hindsight jurisprudence"). The language of that Court in Dembiczak, already quoted above, bears repeating because of its applicability to this case:

> Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. . . . Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of hindsight.

Dembiczak, 175 F.3d at 999. This quite aptly describes what Mylan has done here. Dr. Anderson took the inventor's disclosure as a blueprint for piecing together the prior art.[3] This is the prototypical hindsight-based obviousness analysis. It is unacceptable under well-settled

[3] This will be seen further in the next section. Mylan's obviousness theories link the discovery of topiramate to the search for a diabetes cure. Yet Mylan offers nothing to link topiramate with diabetes other than Dr. Maryanoff's New Product Conception Record. Were it not for Dr. Maryanoff's statements about the path he took, there would be no link in the record between diabetes and the patent. Despite Mylan's assertions that Anderson provided an analysis independently of any motivation that Dr. Maryanoff had, neither Mylan nor Dr. Anderson has offered even a theory – no less evidence – linking diabetes and the patent, that does not depend on Dr. Maryanoff's thinking.

Federal Circuit law.

B. The problem of the starting point, and the gaps that follow

As discussed in detail in this Court's preliminary injunction Opinion of October 23, 2006, Mylan has offered two related theories of the obviousness of the invention. (Opinion of October 23, 2006 at 9, 11-12.) Each theory contains multiple gaps, but only one gap need be demonstrated to prove fatal to Mylan's argument.[4] This Court chooses to examine the problem at the beginning, examining the issues around the starting point of the analysis. These issues by themselves show that Ortho must prevail over Mylan as a matter of law. Even without examination of Dr. Anderson's subsequent steps down Dr. Maryanoff's path, the starting point is, as Ortho contends, fatally flawed.

Mylan claims that its analysis "begins where a proper obviousness analysis must begin: with the problem facing the person of ordinary skill in the art." (Defs.' Opp. Br. 13.) This is not the case. To the contrary, Mylan states that the analysis begins with Dr. Maryanoff being assigned the task of formulating a FBPase inhibitor as a potential treatment for diabetes.[5] (Defs.' Rule 56.1 Stmt. ¶ 12.) Mylan does not present evidence – or even argument – to support the claim that this shows the problem facing the person of ordinary skill in the art.

Moreover, Mylan's definition of the starting point is not supported by the statements of

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[4] Dr. Anderson proposed his first theory in his expert report of April 27, 2005. (Anderson Decl. Ex. A.) He proposed a modification of this theory in his declaration of August 23, 2006. Although the theories differ on a number of points, they share the same starting point, and, as the discussion that follows will show, the same defect.

[5] Ortho objects that the problem to be solved here concerns epilepsy, not diabetes. (Pl.'s Br. 10.) This may be a valid point, but this Court need not reach that issue to rule on this motion. Mylan's obviousness theories begin with a diabetes problem. It is sufficient for this Court to find that Mylan's theories are fatally flawed without having to find every defect in them.

its expert, Dr. Anderson. As already quoted, Dr. Anderson makes these statements about the starting point:

> Materials produced during discovery indicate that in early 1978 Dr. Maryanoff became interested in the possibility of preparing inhibitors of the enzyme [FBPase]. He thought such inhibitors might be useful in controlling the level of blood sugar (glucose) in diabetic patients, since FBPase is a key enzyme in the metabolic pathway used by our bodies to produce glucose from nonsugar precursors.

(Anderson Decl. Ex. A. ¶ 11.) This says nothing about Dr. Maryanoff being assigned a task. Rather, it presents a starting point that may be understood as logically consisting of two component steps. First, Dr. Maryanoff was faced with the problem of controlling the level of glucose in diabetic patients. As a matter of logic, this must come first. At the second step, as an approach to solving that problem, Dr. Maryanoff thought to prepare inhibitors of the enzyme FBPase.

Crucially, Mylan has skipped over the first step and begun its theories with the second. This is starting, if not midstream, then at least ankle-deep. The problem faced by the inventor can only be a starting point for the analysis if it is a problem that would have been known to one of ordinary skill in the art at the time the invention was made. 35 U.S.C. § 103(a). Mylan offers no evidence that one of ordinary skill in the art would have recognized as a problem this second step, the question of how to formulate a FBPase inhibitor as a potential treatment for diabetes. Mylan has failed to address the question antecedent to the second step: would one of ordinary skill in the art have recognized a relationship between diabetes treatments and FBPase inhibitors? See Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 882 (Fed. Cir. 1998) (discussing questions of the starting point and antecedent questions in an obviousness analysis).

In contending that the problem to be solved by the inventor was that of finding a FBPase inhibitor to treat diabetes, Mylan ignores what must logically and legally be the true starting point: the problem facing one of ordinary skill in the art, as specified in § 103(a). This is a fatal legal error. Mylan aptly quotes from In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998): "the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." This quote, however, works against Mylan because, as the Rouffet Court explained, "[o]bviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains." Id. It cannot be assumed that the ordinary artisan would have had the insight that FBPase inhibitors might be used to control the blood sugar of diabetics. Rather, the starting point for Mylan's analysis must be step one, which can more reasonably be assumed to have been a problem faced by one of ordinary skill in the art, not step two.[6]

Close examination of just these two steps – setting aside the many steps that follow – shows the fatal defect in Mylan's case. Mylan has not established that, beginning at step one, one of ordinary skill in the art would have either known of step two, or had a motivation or suggestion to reach it. Dr. Anderson's expert report credits Dr. Maryanoff with the idea that

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[6] Even if the second step were considered to define the problem to be solved, Mylan would still face the obstacle of showing that this problem was known in the prior art. The Federal Circuit recognizes that "[t]here can of course arise situations wherein identification of the problem is itself the invention." Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 381 F.3d 1371, 1377 (Fed. Cir. 2004). In Cardiac, the Court stated that, when a problem is well-recognized, identification of the problem is not an invention. Id. As already discussed, Mylan has presented no evidence that the art recognized the problem of finding a FBPase inhibitor for the purpose of treating diabetes.

FBPase inhibitors might be useful in controlling blood sugar in diabetic patients. (Anderson Decl. Ex. A. ¶ 11.) In his subsequent declaration, Dr. Anderson shifts his approach, contending that "the idea of inhibiting FBPase was hardly novel at the time of the claimed invention," and pointing to Maryanoff's citation of the prior art work of Benkovic, who had designed FBPase inhibitors. (Anderson Decl. ¶ 5.) Yet this does not get Mylan from step one to step two. The fact that the prior art knew of FBPase inhibitors does not show that the use of FBPase inhibitors to control blood sugar in diabetic patients was known. As Ortho observes, the Benkovic reference says nothing about diabetes. (Lohrenz Decl. Ex. E.) New uses of existing compounds are, of course, patentable. Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1378 (Fed. Cir. 2005) ("New uses of old products or processes are indeed patentable subject matter"). Dr. Danishefsky opined that Dr. Maryanoff's idea of looking to an FBPase inhibitor for the treatment of diabetes was "ingenious." (Danishefsky Decl. ¶ 6.)

The question of how to get from step one to step two requires application of the "motivation-suggestion-teaching" test. Kahn, 441 F.3d at 986. To prevent hindsight analysis, Mylan must show that one of ordinary skill in the art would have found a motivation, suggestion, or teaching to look to FBPase inhibitors as a means of controlling blood sugar in diabetic patients. In Pro-Mold v. Great Lakes Plastics, 75 F.3d 1568, 1573 (Fed. Cir. 1996), the Federal Circuit held that the motivation or suggestion may be found in three different places: 1) "[s]uch a suggestion may come expressly from the references themselves;" 2) "[i]t may come from knowledge of those skilled in the art;" and 3) "[i]t may also come from the nature of a problem to be solved." Id. See also Rouffet, 149 F.3d at 1357 ("This court has identified three possible sources for a motivation to combine references: the nature of the problem to be solved, the

teachings of the prior art, and the knowledge of persons of ordinary skill in the art"). Neither Mylan nor Dr. Anderson has offered evidence that the suggestion to use Benkovic's FBPase inhibitors to solve the problem of controlling blood sugar in diabetic patients was present in any of these sources.

Significantly, Mylan contends that it has offered such evidence in the statements of Dr. Anderson, but this is incorrect; the record Mylan points to does not show what it claims. In its brief, Mylan contends: "Dr. Anderson opines that a person of ordinary skill in the art interested in treating diabetes, *i.e.* the control of sugar levels, would be led to seeking [sic] ways to inhibit the enzyme FBPase, because of its particular role in controlling just those levels." (Defs.' Opp. Br. 14.) For support, the brief cites to ¶¶ 13-14 in Defendants' Rule 56.1 statement, which cite to the Anderson Decl. at ¶ 5 and Anderson Decl. Ex. A at ¶ 11. Neither of these Anderson sources supports Mylan's claim. In ¶ 11 of his expert report, Dr. Anderson states – as already quoted – that Dr. Maryanoff thought that FBPase inhibitors might be useful in controlling the blood sugar of diabetic patients. There is no assertion that one of ordinary skill in the art would have had that idea. In ¶ 5 of his subsequent declaration, Dr. Anderson states that Dr. Maryanoff's New Product Conception Record cites the Benkovic reference, which discloses the design of FBPase inhibitors. Dr. Anderson makes no claim that Benkovic – or anyone other than Dr. Maryanoff – disclosed using an FBPase inhibitor for diabetes treatment.

This is a key problem, for Mylan uses this to argue that Dr. Anderson's testimony shows the existence of a factual issue as to whether the person of ordinary skill in the art interested in treating diabetes would have sought to use an FBPase inhibitor for this purpose. Since Dr. Anderson does not support Mylan's claim, however, Mylan has failed by this argument to raise a

material factual issue sufficient to defeat summary judgment.

The question at summary judgment is whether there is a genuine factual dispute that prevents resolution of the obviousness issue as a matter of law. Mylan bears the burden of proof of patent invalidity at trial. As the moving party without the burden of proof, Ortho has carried its initial summary judgment burden by pointing to the absence of evidence to support Mylan's case. The burden then shifts to Mylan, which must present actual evidence that creates a genuine issue as to a material fact for trial. Anderson, 477 U.S. at 248. As discussed above, Mylan has offered no evidence that there was a suggestion from any source to use FBPase inhibitors to solve the problem of controlling blood sugar in diabetic patients; the requirements of the "motivation-suggestion-teaching" test have not been met.[7] Federal Circuit law requires "rigorous application" of this test in an obviousness analysis. Dembiczak, 175 F.3d at 999. Mylan has not shown a genuine issue as to any material fact; rather, there is a complete failure of proof concerning an essential element of the nonmoving party's case. On the issue of the invalidity of claim 1 due to obviousness, Ortho is entitled to partial summary judgment as a matter of law, and its motion for partial summary judgment will be granted.

Because this analysis by itself is sufficient to decide the instant motion, this Court need not scrutinize the remaining steps in Mylan's obviousness theory. As discussed in detail in this Court's preliminary injunction Opinion of October 23, 2006, Mylan has offered two different theories, and each has numerous gaps similar to the one just described. (Opinion of October 23, 2006 at 9, 11-12.) The theories suffer from multiple defects, any one of which is sufficient to

[7] Had Mylan shown evidence of motivation, it would next have to clear the hurdle of showing a reasonable expectation of success. Medichem, 437 F.3d at 1165. Since Mylan has not produced evidence of motivation, this next issue is not reached.

prevent Mylan from carrying its burden of proving invalidity by clear and convincing evidence.

Mylan cannot prove that claim 1 is invalid due to obviousness. Claim 1 is the only independent claim in the '006 patent. Because the remaining claims are all dependent on claim 1, those claims cannot be shown to be obvious in the absence of showing claim 1 to be obvious. See In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992) ("dependent claims are nonobvious if the independent claims from which they depend are nonobvious"). Because of the statutory presumption that a patent is valid, Ortho must prevail. 35 U.S.C. § 282. On the issue of the invalidity of the patent due to obviousness, Ortho is entitled to partial summary judgment as a matter of law, and its motion for partial summary judgment will be granted in its entirety.

CONCLUSION

For the reasons stated above, as to Mylan's defense of patent invalidity due to obviousness, Ortho has demonstrated that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). Ortho's motion for partial summary judgment on Mylan's invalidity defense of obviousness is **GRANTED**.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: February 2, 2007